

A' dialyzer is then drained by opening the valves 230 and 237. At the end of the rinse cycle, the dialyzer 211a is filled with a liquid sterilant from a reservoir 234 using a pump 235 and a valve 236 to enter the dialysate inlet 207a, exiting through port 210a.

IN THE CLAIMS

Please cancel original claims 1-24 and substitute the following claims.

--25. A method for removing contaminant materials from hollow tubing and piping walls comprising

A² forming a two phase flow of a cleaning solution and a gas at high velocity in at least a portion of said tubing or piping so as to form droplets along the walls of said tubing or piping, wherein said droplets create shear and impact stresses on said walls sufficient to loosen contaminant materials from said walls and

flushing said tubing or piping to remove the loosened materials.

26. A method according to claim 25 wherein the liquid to gas ratio is from about 1:50 to about 1:6000.

27. A method according to claim 25 wherein said cleaning solution is basic.

28. A method according to claim 25 wherein the cleaning solution is acidic.

29. A method according to claim 25 wherein the cleaning solution includes a surfactant.

30. A method according to claim 25 wherein the cleaning solution includes an oxidizing agent.

31. A method according to claim 25 wherein said flushing is performed with a two phase flow mixture of water and air.

32. A method according to claim 25 wherein, after flushing, said hollow tubing or piping is sanitized with a two phase mixture of a liquid sanitizing agent and air.

33. A method according to claim 25 wherein said tubing or piping is dried using flowing air.

34. A method according to claim 25 wherein said contaminants are dairy residues.

35. A method of removing contaminants from the pores, lumens and under-the-cap regions of a hemodialyzer including a hollow fiber membrane bundle comprising

backflushing the hollow fiber membrane bundle with a

cleaning solution by pressurizing the cleaning solution from the dialysate side of the dialyzer,

passing a gas under pressure into the lumen side of the dialyzer so as to form a two phase flow mixture with the backflushed cleaning solution that produces droplets that create shear or impact stresses on the lumen walls of the hollow fibers, and wherein said two phase flow mixture creates turbulence inside the under-the-cap regions of the hemodialyzer, thereby loosening and removing said contaminants from the dialyzer.

36. A method according to claim 35 wherein the cleaned dialyzer is rinsed with deionized water and filled with a liquid sterilant.

37. A method according to claim 35 wherein said cleaning solution includes an agent that unclogs the pores and lumens of the hollow fiber membranes.

38. A method according to claim 35 wherein said cleaning solution includes a chelating agent.

39. A method according to claim 35 wherein said cleaning solution is made with sodium hydroxide.

40. A method according to claim 35 wherein said cleaning solution has a temperature in the range of 20 to 60 degrees Centigrade.

41. A method according to claim 35 wherein said cleaning solution includes a surfactant.

42. A method according to claim 35 wherein said cleaning solution has a pH of at least 7.0.

43. A method according to claim 35 wherein said cleaning solution includes an oxidizing agent selected from the group consisting of a peroxy compound having an acidic pH.

44. A method according to claim 35 wherein said cleaning solution includes an oxidizing agent selected from the group consisting of a hypochlorite compound.

45. A method according to claim 35 wherein the direction of the two phase flow is periodically reversed.

46. A method according to claim 35 wherein the two phase flow is pulsed by stopping the flow of air periodically while backflushing continues.

47. A method according to claim 35 wherein a pre-mixed liquid-gas two phase flow mixture is applied to the lumen side of the dialyzer prior to commencing the backflushing step.

48. A method according to claim 35 wherein the two phase flow cleaning is preceded by backflushing with a cleaning liquid alone.

49. A method of removing contaminants from pores, lumens and under the cap regions of a hemodialyzer including hollow fibers comprising

pressurizing a cleaning solution from the dialysate side of the hemodialyzer,

passing a premixed mixture of a liquid and a gas into the lumen side of the hemodialyzer,

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cont* combining said cleaning solution and said liquid-gas mixture so as to generate droplets that create shear or impact stresses that sweep the interior walls of the hemodialyzer fibers to remove the contaminant.

50. A method according to claim 49 wherein the cleaned dialyzer is rinsed with deionized water and filled with a liquid sterilant.

51. A method according to claim 49 wherein the cleaning solution and the liquid used to form the liquid-gas mixture are the same.

52. A method according to claim 49 wherein the cleaning solution and the liquid used to form the liquid-gas mixture are different.

53. A method according to claim 49 wherein the liquid used to form the liquid-gas mixture includes an agent that unclogs the lumens of the hollow fibers of the dialyzer.

54. A method according to claim 53 wherein said agent is selected from the group consisting of heparin and a citrate solution.

55. A method according to claim 49 wherein said cleaning solution includes a chelating agent.

56. A method according to claim 49 wherein said cleaning solution includes a surfactant.

57. A method according to claim 49 wherein said cleaning solution has a pH of at least 7.0.

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cont 58. A method according to claim 49 wherein said cleaning solution includes a peroxy compound oxidizing agent, said solution having an acid pH.

59. A method according to claim 49 wherein said cleaning solution includes a hypochlorite compound oxidizing agent.

60. A method according to claim 49 wherein said cleaning solution includes sodium hydroxide.

61. A method according to claim 49 wherein said cleaning solution has a temperature of from 20 to 60 degrees Centigrade.

62. A method according to claim 49 wherein the direction of two-phase flow is periodically reversed.

63. A method according to claim 49 wherein the two-phase flow cleaning is preceded with a backflushing using cleaning liquid

alone.

64. A method according to claim 49 wherein the two-phase flow cleaning is followed by backflushing using a cleaning solution alone.

65. A method of removing contaminants from the lumen and under-the-cap regions of a hemodialyzer including hollow fibers comprising

*Az
cont* passing a pre-mixed mixture of a cleaning solution and a gas into the lumen side of the hemodialyzer so as to generate droplets that create shear or impact stresses on the lumen walls of the hollow fibers, and wherein said mixture creates turbulence inside the under the cap regions of the hemodialyzer, thereby loosening and removing said contaminants from the hemodialyzer.

66. A method according to claim 65 wherein the cleaned hemodialyzer is rinsed with deionized water.

67. A method according to claim 65 wherein said cleaning solution includes a chelating agent.

68. A method according to claim 65 wherein said cleaning solution includes a surfactant.

69. A method according to claim 65 wherein said cleaning solution has a pH of at least 7.0.

70. A method according to claim 65 wherein said cleaning solution includes a surfactant.

71. A method according to claim 65 wherein said cleaning solution includes a hypochlorite compound oxidizing agent.

72. A method according to claim 65 wherein said cleaning solution includes sodium hydroxide.

73. A method according to claim 65 wherein the temperature of said cleaning solution is in the range of 20 to 60 degrees Centigrade.

74. A method according to claim 65 wherein the direction of the two-phase flow is periodically reversed.

75. A method according to claim 65 wherein the two-phase flow cleaning is preceded by backflushing using a cleaning liquid alone.

76. A method according to claim 65 wherein the two-phase flow cleaning is followed by a backflushing using a cleaning liquid alone.

77. A method for removing blood proteins and contaminants from a contaminated hemodialyzer comprising

backflushing the hemodialyzer with a cleaning solution having a pH of at least 7.0 from the dialysate side of the

hemodialyzer to loosen the contaminants, passing another liquid into the lumen side of the hemodialyzer and flushing the contaminants out of the hemodialyzer from the lumen side.

78. A method according to claim 77 wherein said cleaning solutions from the lumen side and the dialysate side are the same.

79. A method according to claim 77 wherein said cleaning solutions from the lumen side and the dialysate side are different.

80. A method according to claim 77 wherein said cleaning solutions include a chelating agent.

81. A method according to claim 77 wherein said cleaning solutions include a surfactant.

82. A method according to claim 77 wherein said cleaning solutions have a pH of at least 7.0.

83. A method according to claim 77 wherein said cleaning solutions include a peroxy compound oxidizing agent having an acidic pH.

84. A method according to claim 77 wherein said cleaning solutions include a hypochlorite compound.

85. A method according to claim 77 wherein said cleaning

solutions comprise sodium hydroxide.

86. A method according to claim 77 wherein the temperature of the cleaning solutions is in the range of 20 to 60 degrees Centigrade.

87. A method according to claim 77 wherein the direction of flow of the cleaning solutions is periodically reversed.

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cont
88. An apparatus for cleaning a dialyzer comprising
a two-phase flow dialyzer reprocessing tank having an inlet for one or more aqueous cleaning solutions, an inlet for air, an inlet for a flushing solution and an inlet for a liquid sterilant,

means for backflushing a cleaning solution through the dialysate side of a dialyzer;

means for forming and delivering a two phase flow of cleaning solution and air to the dialyzer to remove contaminants therefrom;

means for delivering a gas to the dialysate side of the dialyzer;

means for flushing the dialyzer; and

means for filling the dialyzer with a liquid sterilant.

89. An apparatus according to claim 88 wherein the air used to

form the two-phase flow has positive pressure.

90. An apparatus according to claim 88 wherein the air used to form the two-phase flow has negative pressure.

91. An apparatus according to claim 88 wherein the two-phase flow is directed to a mist separator which separates solution and gas.

Az 92. An apparatus according to claim 88 which includes a means of pressurizing the cleaning solution from the dialysate side of the dialyzer.

93. An apparatus according to claim 88 wherein the two phase flow mixture is formed by passing a cleaning solution from the dialysate side and mixing it with gas from the lumen side.--

REMARKS

The claims are now 25-93.

The specification on page 27 line 13 et seq has been corrected. A clean copy of the amended paragraph is set forth hereinabove. A copy of the paragraph as corrected is attached hereto, using brackets to delete material and underlines to add material.

An early action on the merits of the application is